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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-----------------|----------------------|-----------------------|------------------|
| 10/645,328 | 08/21/2003 | Rodolfo R. Llinas | 05986/100K521-US1 | 7569 |
| 7278 | 7590 01/24/2006 | | EXAMINER | |
| DARBY & DARBY P.C. | | | NATNITHITHADHA, NAVIN | |
| P. O. BOX 5257 | | | ART UNIT | PAPER NUMBER |
| NEW TORK, | N1 10130-3237 | | 3736 | |
| NEW YORK, NY 10150-5257 | | | | I AI EK NOWDEK |

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--|--|---|--|--------------|--|--|
| | | Application No. | Applicant(s) | | | |
| | | 10/645,328 | LLINAS, RODOLI | FO R. | | |
| O | ffice Action Summary | Examiner | Art Unit | | | |
| | | Navin Natnithithadha | 3736 | | | |
| The Period for Rep | MAILING DATE of this communication oly | appears on the cover sheet | with the correspondence ac | ddress | | |
| THE MAILI - Extensions of after SIX (6) - If the period of the service of the ser | ENED STATUTORY PERIOD FOR RE NG DATE OF THIS COMMUNICATION of time may be available under the provisions of 37 CF MONTHS from the mailing date of this communication for reply specified above is less than thirty (30) days, a for reply is specified above, the maximum statutory peoply within the set or extended period for reply will, by sleeved by the Office later than three months after the mattern adjustment. See 37 CFR 1.704(b). | DN. R 1.136(a). In no event, however, may n. a reply within the statutory minimum of the statutory minimum of the statutory minimum of the statute, cause the application to become | a reply be timely filed thirty (30) days will be considered time ONTHS from the mailing date of this of ABANDONED (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)⊠ Resp | onsive to communication(s) filed on <u>1</u> | 3 October 2005. | | | | |
| 2a)∐ This | action is FINAL . 2b)⊠ ⁻ | This action is non-final. | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of | Claims | | | | | |
| 4a) O 5)∭ Clain 6)∭ Clain 7)∭ Clain | n(s) <u>1-36</u> is/are pending in the applicant the above claim(s) is/are with n(s) is/are allowed. n(s) <u>10-17,28 and 29</u> is/are rejected. n(s) <u>1-9,18-27 and 30-36</u> is/are objectin(s) are subject to restriction are | drawn from consideration. ed to. | | | | |
| Application Pa | apers | | | | | |
| 10)☐ The d Applie | pecification is objected to by the Exan rawing(s) filed on is/are: a) | accepted or b) objected the drawing(s) be held in abey | vance. See 37 CFR 1.85(a). | 50 4 4044 1) | | |
| | ncement drawing sheet(s) including the collater at the collate | • | * ' ' ' | , , | | |
| Priority under | 35 U.S.C. § 119 | | | | | |
| a) | Copies of the certified copies of the application from the International Bu | nents have been received. nents have been received in priority documents have bee reau (PCT Rule 17.2(a)). | Application No en received in this National | Stage | | |
| see tn | e attached detailed Office action for a | nst of the certified copies n | ot received. | | | |
| Attachment(s) | | П | | | | |
| 2) 🔲 Notice of Dr | eferences Cited (PTO-892) aftsperson's Patent Drawing Review (PTO-948) Disclosure Statement(s) (PTO-1449 or PTO/SE //Mail Date |) Paper N | w Summary (PTO-413) lo(s)/Mail Date of Informal Patent Application (PT | O-152) | | |

DETAILED ACTION

Response to Amendment

1. Claims 1, 10, and 18 have been amended. Claims 37 and 38 have been cancelled. Claims 1-36 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 October 2005 has been entered.

Response to Arguments

3. Applicant's arguments with respect to claims 10-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 3736

Claims 10, 14, 28, and 29 are rejected under 35 U.S.C. 102(b) as being 4. anticipated by Alt, US 5,143,089 A (hereinafter referred to as Alt).

Page 3

Claims 10, 14, 28, and 29: Alt teaches a device (see fig. 1), comprising: a catheter (guide catheter) 17; and an electrode (a fiber electrode consisting of a plurality of electrically conductive polymer fibers 2 or fiber strands 3) 1a, wherein a signal on the electrode is monitored by way of a wire (electrical conduction lead) 5 connected to the electrode 1a, the signal being indicative of the electrical activity of the heart and being deployed from the catheter 17 in the heart. The limitations of "for sensing the activity of neural tissue," "being deployed from the catheter in a blood vessel proximate to the neural tissue," "being indicative of the electrical brain activity of the neural tissue," "being operative to provide a stimulation signal to the neural tissue," "placed in a second blood vessel proximate to the neural tissue," "capable of being inserted into a capillary," and "being operative to provide stimulation signal to said neural tissue" are functional limitations of the apparatus claimed. Using this language is a recitation of the intended use of the claimed invention, which must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The size of each fiber strand 3 have a thickness as low as 8 to 20 microns, thus can be smaller than 10 microns. The small size allows the fiber 3 to be used in blood vessels/capillary proximate to neural tissue and thus is capable of placement in the

blood vessels/capable to indicate electrical brain activity. Therefore, Alt anticipates claims 10, 14, 28, and 29.

Page 4

5. Claims 11, 12, 15, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by Alt or, in the alternative, under 35 U.S.C. 103(a) as obvious over Alt in view of Kovacs et al, US 5,883,603 A (hereinafter referred to as Kovacs) and/or John, US 4,913,160 A (hereinafter referred to as John).

<u>Claims 11, 12, 15, and 16</u>: Alt teaches a therapeutic instrument 19 which would inherently have the typical components of a computer to receive and process the signal from the electrodes. However, in the alternative, Kovacs and John teach devices which have amplifiers, digital converters, multiplexers, and microprocessors for coupling to an electrode in order to provide signal processing.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over et al, US,, B1A (hereinafter referred to as), as applied to claim 12 above, and further in view of over Hoek, US 6,615,067 B2 (hereinafter referred to as Hoek).

<u>Claims 12 and 13</u>: Alt does not teach a Schmitt trigger. However, use of a Schmitt trigger for converting analog signals to digital signals is well known in the art. For example, Hoek teaches a Schmitt trigger 307 connected to a filter 306 (see col. 6, lines

Application/Control Number: 10/645,328 Page 5

Art Unit: 3736

24-29). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Alt's circuitry to include a Schmitt trigger in order to have accurate digital processing of an electrode signal.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt, as applied to claim 16 above, and further in view of Lieber et al, US 2002/0117659 A1 (hereinafter referred to as Lieber).

Claim 17: Alt teaches electrodes that are between 8-20 microns but does not explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Alt's electrodes in order to reduce the size of the electrodes and thus limiting obstruction when inserted into the body.

Allowable Subject Matter

- 8. Claims 1-9, 18-27 and 30-36 are allowed.
- 9. The following is an examiner's statement of reasons for allowance:

Claims 1-9, 26, 27, and 32-36: The prior art of record does not teach a method of sensing the activity of neural tissue comprising placing an electrode smaller than 10 micrometers in a blood vessel proximate to the neural tissue and monitoring a signal on

the electrode, wherein the signal is indicative of the electrical brain activity of the neural tissue.

<u>Claims 18-25, 30, and 31</u>: The prior art of record does not teach a method of stimulating neural tissue comprising placing an electrode smaller than 10 micrometers in a blood vessel proximate to the neural tissue and providing a signal on the electrode, wherein the signal stimulates the electrical brain activity of the neural tissue.

Alt only provides a method step of using an electrode having a size between 8-20 microns for stimulating or monitoring cardiac tissue.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,129,685 A teaches some of the subject matter in the Applicant's claims. The Examiner suggests reviewing these patents in responding to this Office Action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

Application/Control Number: 10/645,328 Page 7

Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha Patent Examiner

GAU 3736

23 January 2006